



Florida Memorial University

**Institutional Review Board
Procedure Manual for Research with Human Subjects**

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Chapter 1: History and Purpose

Introduction

Florida Memorial University (FMU) encourages research and scholarship in and among its colleges and centers and in collaboration with other educational institutions, agencies, and organizations. In this regard, the university, while respecting the right of faculty to full academic freedom in research, is firmly committed in adhering to the basic ethical principles underlying the acceptable conduct of research involving human subjects, as set forth in [*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*](#). These three principles, respect for persons, beneficence, and justice, are relevant particularly to the protection of human subjects in biomedical and behavioral research, and are the accepted requirements for the ethical conduct of such research.

- Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
- Beneficence entails an obligation to protect persons from harm by maximizing anticipated results and minimizing possible risks of harm.
- Justice requires that the benefits and burdens of research be distributed fairly.

Moreover, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to minimize risks; and the principle of justice requires that subjects be fairly treated.

The university has set standards for the conduct of research that mandate well-conceived and well-conducted research. To assist in maintaining those standards, an Institutional Review Board (IRB) has been established, and this *Policy and Procedure Manual for Research with Human Subjects* has been prepared for distribution to the university community. The manual provides detailed information to support institutional initiatives for guaranteeing compliance with federal regulations governing the protection of human subjects and to guide principal investigators in procedures relevant to the development of research protocols that include human subjects. Throughout this manual, humans whose 1) physiologic or behavioral characteristics, 2) understanding of their lived experiences, 3) and/or responses are the object of study are referred to as subjects; however, the university in no way intends to demean the humanity and individualism of such persons. Recognizing that regulations and policies and procedures are no guarantee of ethical conduct, it is the responsibility of individual researchers to make ethical considerations central in the conduct of research and to have a clear understanding of their duties to human subjects.

This *Procedure Manual for Research with Human Subjects* was developed under the direction of the Institutional Review Board Task Force established by the university's Assistant Provost for Academic Affairs in the Spring 2005. Special recognition and thanks are extended to the members of the Task Force for their commitment of time and significant contributions to the development of this document.

Responsibility

IRB Responsibility

The Florida Memorial University Institutional Review Board (FMU-IRB) was established to respond to The National Research Act Public Law 99-158, and continues to function in response to the most recent extension of that law, The Health Research Extension Act of 1985. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has set forth guidelines, specifically, the Belmont Report and Title 45, Part 46 of the Code of Federal Regulations, to guide research with human subjects and ensure their protection in the design and conduct of research.

These federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that such research is reviewed and approved by the university's Institutional Review Board. The university's administration has made the decision that all research with human subjects, whether funded or unfunded, or subject to federal regulation or not, will be reviewed and approved in accordance with the guidelines set forth in this manual.

The IRB is responsible for determining and assuring, under the auspices of FMU faculty, staff, and students, that:

- the welfare and rights of human subjects are adequately protected and informed consent given, if necessary;
- human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research;
- the necessity and importance of the research outweighs the risks to the subjects;
- and the researcher(s) is/are qualified to conduct research involving human subjects.

Investigator Responsibility

The FMU-IRB expects that investigators will not only submit new protocols for review, but also submit requests for continuation, revisions, and ultimately final reports (when appropriate) as a part of conducting research at or with FMU. Investigators are also responsible for reporting violations to study protocols as well as reporting adverse events. FMU expects researchers to conduct research in an ethical and legal manner, adhering to applicable regulations (federal, state, and local) as well as accepted principles of good research.

Certifications and Records

Certification of IRB Review (for Funded Projects only)

Certification of IRB review refers to the official notification by the university to the Department of Health and Human Services (DHHS) that research activities or projects involving human subjects have been reviewed by the IRB. Under the DHHS human subjects protection regulations at 45 C.F.R. 46.103, every institution engaged in human subjects research supported or conducted by DHHS must obtain an assurance of compliance approved by the Office for Human Research Protections (OHRP).

Historically, OHRP has approved three basic types of assurances: Multiple Project Assurance (MPA), Cooperative Project Assurance (CPA), and Single Project Assurance (SPA). All MPAs approved by OHRP were designated for federal-wide use. In December 2000, OHRP developed an Institutional Review Board (IRB) Registration and a new Federal Wide Assurance (FWA) intended to: 1) create a new registry of IRBs, and 2) streamline the assurance process to significantly reduce the administrative burden on individual institutions, other federal departments and agencies, and OHRP.

FMU will be submitting its FWA and registering its IRB and will be in full compliance with this regulation by August 12, 2005.

Records

It will be the responsibility of the IRB Chair (also referred to as "Chair" in this document) or the Chair's designee to prepare and/or maintain adequate documentation of IRB activities regarding research involving human subjects, including the following:

- Copies of all research proposals reviewed and actions taken, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects
- Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining (including the reason for the abstention); the basis for requiring changes in or disapproving research; and a written summary of issues of dispute and their resolution; information related to all studies approved at the expedited level; reporting of any adverse events and all discussion regarding the adverse events
- Records of continuing review of research activities
- Copies of all correspondence between the IRB and investigators
- A list of all IRB members, including their name, race, ethnicity, and gender; earned degrees; affiliation to the university; academic unit/center they represent

(i.e., Center for Psychological Studies, Health Professions Division-College of Osteopathic Medicine, etc.); indications of experience, such as board certifications, licenses, etc.

- Written procedures governing the IRB

Copies of all documentation regarding research reviewed by the IRB will be maintained in the university Office of Grants and Sponsored Programs. All records are retained for at least three (3) years. Records relating to funded research conducted are retained for at least three years after completion. Investigators are responsible for maintaining signed consent form documents for a period of 3 years from the date the study concluded.

Chapter 2: Policies and Structure

IRB Membership

The IRB consists of members with varying professional, racial, ethnic, cultural, and gender differences, who are knowledgeable about professional regulations and conduct and are sensitive to community attitudes. All voting members are university employees who are full-time faculty members and who have experience in higher education or are appointed members of the community. At least one voting member of the Board shall be a non-scientist and one shall be a member of the community. The members shall consist of:

- The IRB Chair (which will be the IRB Director for the 2005-2006 school year)
- One member from each college, preferably a full-time faculty member, and their duly appointed alternates
- Two additional members from the University and/or the wider community.

The IRB also has non-voting/ex-officio members which include the Provost and the Director of the Office of Grants and Sponsored Programs.

All members and alternates of the Board will be appointed by the Provost of Academic Affairs to staggered two-year terms. Members and alternates of the Board will be notified of their appointments by the Provost. A quorum is defined as a majority of voting members (one more than half the voting members).

No member of the IRB may participate in the review and approval process for any project in which he or she has a present or potential conflict of interest. Any IRB member or alternate whose name appears anywhere in the application or if they have any reason to believe they will have a role in the research are automatically excused. Any IRB member or alternate who feels he or she might not be completely objective in doing the review for any reason may excuse himself or herself. Where the investigator-member has a conflicting interest, he or she should be absent from the meeting room during discussion and voting phases of the review and approval process; IRB minutes will reflect whether or not these requirements have been met.

Furthermore, when the IRB reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons) or research for which no members possess the necessary qualifications to review the IRB may include one or more individuals with specific knowledge and experience appointed temporarily for the project's review. Such individuals may not vote with the IRB in these instances. The IRB also requires that the review of research involving prisoners include a prisoner advocate during the Board's discussion.

The IRB Chair is granted appropriate release time from his/her assigned teaching responsibilities for the term of the appointment. Staff support is provided to the Chair by

the IRB Administrator and Support Staff to the IRB who are a part of the Office of Grants and Sponsored Programs.

Alternates may attend Board meetings in the company of their College Representatives. However, when accompanying their College Representatives, alternates may neither participate in the discussion nor vote. When the alternate is replacing a College Representative, the College Representative should notify the IRB office so that the alternate may be given a full IRB packet in advance of each meeting in order to prepare for participation in the discussion and vote.

Functions and Operations

Meetings

Meetings of the IRB are convened by the Chair, or the Chair's designee, at a minimum of once a month. For regular meetings, members shall receive at least five (5) days' notice, including the distribution of complete study documentation for review. If there is no IRB business for the month, the Chair, or other designee, may cancel the meeting and notify all members of such action. Emergency meetings may be convened, as appropriate, and require at least 48 hours' notice. There must be seven (7) of the IRB voting members, one of whom must be a non-scientist, present at the meeting to constitute a quorum and for the meeting to be official. The Chair will vote only in the event of a tie.

Members of the board are notified of decisions made at the expedited level via the minutes provided at the meeting.

Training

All new appointees to and continuing members of the IRB will receive training. The Chair, and/or others the Chair deems appropriate, will be responsible for training new appointees to the IRB. Members must make a commitment to participate not only in initial training, but also to participate in ongoing training and to facilitate training for other faculty, staff, and students within the university, as appropriate. All individuals involved in research with human subjects and/or in the university's human subjects' protection program must complete the Assurance Training Modules.

Changes in Policies and Procedures

Policies and procedures governing the IRB may be changed at a regularly convened IRB meeting by a vote of the majority of the Board members present, based on a quorum of one more than half of the voting members present. Any changes are to facilitate the effective and efficient operation of the IRB and in no way conflict with the rules and regulations set forth in federal statutes and regulations relating to the protection of human subjects. Substantive changes will be submitted to the Provost of

Academic Affairs for review and approval. Any changes in policy and procedures shall be distributed to all members and shall be included as (an) amendment(s) to this manual. Policies are distributed to the university community via college representatives and through the IRB Web site. The Office of Grants and Sponsored Programs will assist in making changes to these policies and procedures and will be responsible for completing and distributing any amendments to this manual. The IRB, in consultation with the Office of Grants and Sponsored Programs reviews regularly the federal guidelines governing research with human subjects, and updates FMU policies, as necessary.

Authorities

Any research that involves human subjects conducted by FMU faculty, staff, or students, whether funded or unfunded, shall be under the jurisdiction of the IRB. Principal investigators who propose human subject research must follow the guidelines for preparing and submitting proposals to the IRB included in this manual. The Chair is authorized to consult with university counsel, as necessary.

Research Subject to Review

To comply with the federal guidelines covering the protection of research subjects, and to ensure appropriate ethical management of research programs conducted by FMU faculty, staff, and students, all funded and unfunded research proposals involving human subjects fall within the jurisdiction of the IRB. This includes all research activities conducted by any student or any employee of FMU that involves human participants in any manner or involves records about clients, students, or employees. Such research activities must be reviewed by the IRB before any research may begin. However, there are multiple levels of review that depend upon the nature of the research, the populations involved, the potential for harm, and the potential for violation of confidentiality rules which control the level of the review. If additional information/clarification is necessary, the IRB Chair or IRB Director should be contacted.

The IRB Director is responsible for determining the level of review that applies to a given research project. The levels of review are discussed in the next chapter. The three possible levels of review include: Exempt Review, Expedited Review, and Full Review. While these guidelines are intended to give a researcher some expectation of the level of review needed, a representative of the IRB must determine the actual level of review for each project. The College Representative is authorized to consult with the Director and/or other members of the IRB about the type of review necessary for a protocol.

Noncompliance

The university's IRB is responsible for reviewing all protocols related to human subject research. The IRB approves those protocols that meet governmental regulations and

university policy. In its approval, the IRB stipulates conditions that the investigator must meet including the time period the study may be conducted before the next IRB review. The IRB expects the investigator to conduct the study as described to the IRB in the research protocol, to follow governmental regulations and university policy, and to adhere to any requirements stipulated in the IRB's approval letter.

Any unanticipated problems involving risks to subjects or any serious or continuing noncompliance with the regulations or requirements of the IRB or federal regulations governing human subjects research must be reported to the Chair of the IRB. The Chair will work with institutional officials in investigating the reported non-compliance.

The formal inquiry will determine the corrective actions required of the investigator in consideration of the nature, severity, and frequency of the noncompliance and the risk(s) that noncompliance poses to human subjects. Institutional officials will determine whether and when to notify the funding source(s), OHRP, FDA, and cooperative research sites. Institutional officials will also determine whether the noncompliance rises to the level of professional misconduct. The institutional officials may consider a range of options to address documented cases of noncompliance.

When the institutional officials determine that specific corrective actions must be implemented, the investigator will be notified in writing. The investigator will be required to acknowledge and implement the corrective action. The research may or may not be allowed to continue, depending on the specific circumstances of the noncompliance. Research that is permitted to continue will do so under the terms outlined by the university as a result of the noncompliance. The IRB may terminate or suspend approved studies in cases of severe noncompliance that affects the rights and welfare of human subjects. Any action taken by the IRB and institutional officials related to noncompliance will be documented and correspondence as to the nature and actions taken will be sent to the respective college/center dean or director

Auditing of studies

The university and the IRB reserve the right to request that studies be audited for compliance with university policy and regulations governing human subjects research. Investigators should also be aware that federal regulatory agencies that govern research with human subjects (Department of Health and Human Services and the Food and Drug Administration) may also audit studies when appropriate. Consent procedures/documents must be sure to communicate to prospective subjects that all documentation pertaining to a study may be audited by regulatory agencies.

The IRB also reserves the right to observe, or have a third party observe, the informed consent process of all approved research.

Concerns and Complaints from Subjects

Subjects should be reminded that concerns and/or complaints about research they are participating in should be directed to either the investigators and/or the IRB. Concerns/complaints received by the IRB will be investigated promptly, and reported to institutional officials as well as any applicable regulatory agencies.

Education versus Research

Federal regulations define research as a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” When research is involved with human subjects, IRB approval must be obtained and consent forms must conform to research guidelines.

The difference between education and research use is often the intent of the user of the information. When the intent is simply to present collected data without generalizing or studying the results, this is usually considered an educational presentation whether it is presented in a classroom or at a workshop. However, when the intent is to generalize beyond the case to general recommendations, procedures, or conclusions, the intent is usually considered to reflect research.

A. Classroom Projects/Assignments

Projects conducted by students, graduate or undergraduate, as a part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to or likely to lead to generalizable results. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures, including research methods (interviewing, observation and survey techniques, as well as data analysis).

Instructors will use their judgment on whether or not to submit protocols for assignments involving human subjects. If they have questions/concerns, they should contact the IRB Chair or their division’s representative. While most assignments for class do not require IRB review, some do as a result of the vulnerability of subjects or the potential risk to subjects. Any research involving vulnerable populations should be reviewed by the course instructor first.

Instructors are advised to discuss these issues with their students and clarifying the role of the IRB should the student be interested in pursuing a research activity that might necessitate IRB review. Instructors should contact college’s IRB Representative for more information.

Instructors are expected to review the proposed research to determine if it meets the definition of student research and is permissible under these guidelines. In instances where a class of students will be conducting group or individual research projects as a

part of the classroom instruction, and the instructor believe that, under our guidelines, IRB approval is required, the instructor shall present for IRB approval one application setting forth the information requested within IRB documents.

Student researchers should also note that if there is any likelihood that the results of the project might want to be later used for research that does lend to generalizable knowledge (for example, within a thesis or a presentation to a group other than the class), IRB approval must be secured prior to conducting the research activities. IRB approval cannot be granted retroactively. It is expected that any data collected as a class project will be destroyed after the grading of the project has been completed.

B. Thesis

Thesis projects involving human subjects are considered research as defined by 45 CFR 46 and require review by the IRB (beginning with the Representative of your college/school). Information related to the IRB process is available on the IRB website and Procedures Manual.

Chapter 3: Procedures/Process

Step-by-Step Process

All research studies involving human subjects are reviewed in one of three ways, Exempt Research, Expedited Review, and Full Review. Every research protocol begins with a complete submission to the primary investigator's respective Center Representative. This individual is charged with reviewing the submission to determine the appropriate level of review for the study as well as assuring that all necessary documents are included. Examples of studies falling into the different types of reviews are found later in this manual.

The College Representative works with the primary investigator to prepare the required IRB documents in accordance with FMU policies/procedures.

These documents include:

- An IRB submission form
- A research protocol (in accordance with the sections defined in the model within this guide).

Additional items which may need to be included are:

- Informed consent forms
- Completed informed consent form checklists
- Evidence of approval by cooperative IRBs at other sites
- Data collection instruments
- Certification of translation for consents or instruments to be used with non-English speaking subjects
- Brochure/recruitment materials

Once a submission is determined as complete, it is submitted in final format to the College Representative who is the starting point for the IRB process.

- If the protocol does not require Expedited or Full Review, the IRB Chair and/or Director will indicate that the study is exempt from further review after all documents are in order. The IRB Director notifies the principal investigator in writing of the determination of exemption. If the study is funded, a copy of the memorandum sent to the principal investigator is forwarded to the Office of Grants and Sponsored Programs.
- If the protocol requires an Expedited Review, the Center Representative will forward to the Office of Grants and Sponsored Programs a complete submission for Expedited Review. The Expedited Review is conducted by the IRB Chair or his/her designee.
- If the protocol requires a Full Review, the College Representative will work with the primary investigator to assure that all documents are in order and will then ask that the primary investigator provide 13 copies of the complete IRB submission.

- In addition, one copy of all research instruments to be used in the study (questionnaires, interviews, surveys, etc.) must be included. The 13 copies (and instruments) will then be forwarded to the Office of Grants and Sponsored Programs. Upon receipt of all required paperwork, the Office of Grants and Sponsored Programs logs the IRB submission, assigns a protocol number, reviews it for completeness, forwards all copies to the IRB members, and places the protocol on the agenda for the next IRB meeting. Any revision requests by the IRB will be sent to the primary investigator via United States postal mail (or campus-wide Interoffice Mail for university faculty/staff). Once IRB approval is granted, the Office of Grants and Sponsored Programs notifies the principal investigator and in the case of funded research the appropriate agency.
- In lieu of paper submissions of documents to be reviewed by the IRB, applicants can send an electronic version of all documents (i.e., application, protocol, Informed consent, and instruments) to the IRB Chair who will then submit documents to the IRB Members. One paper copy, with original signatures must be submitted to the IRB Chair prior to being granted final approval.

For all funded research involving human subjects, the Office of Grants and Sponsored Programs is responsible for coordinating the submission of required documentation to the IRB for review at its next scheduled meeting. The principal investigator has 60 days after submission of the grant proposal to a federal funding agency to obtain IRB approval. The IRB Chair or the Chair's designee, in consultation with the Office of Grants and Sponsored Programs, determines if the research can be reviewed through expedited review.

The IRB conducts continuing review of all research, funded or unfunded, in accordance with the policies and procedures outlined in this manual at intervals appropriate to the degree of risk, but not less than once per year for the life of the project. Federal regulation requires that IRB approved research be reviewed by the IRB by no later than one year from the date of approval—or sooner if the IRB determines that the nature of the research warrants shorter review intervals. No study may continue beyond the one-year approval until the IRB has reviewed the continuation request (see Appendix E). Researchers are also reminded that the IRB may conduct audits at intervals sooner than continuing review periods.

Review of Research Forms

For all research involving human subjects, the principal investigator is responsible for completing the FMU-IRB New Protocol Submission Form (Appendix A) and the Research Protocol (Appendix B). Common attachments include a copy of all proposed

consent forms, any advertising material intended for recruiting subjects, copies of all data collection, survey and test forms, and authorization/approval from IRBs/appropriate personnel at cooperative research sites (if the study is being conducted at sites other than FMU). If the cooperative site does not have an IRB, a statement of willingness to participate must be included.

The FMU-IRB New Protocol Submission Form contains contact information, basic information about the proposed subjects in the study, certain procedures (such as payment to subjects), questions about protected health information, and whether translation is required of consent forms. Certain key issues should be remembered:

- Starting date indicated must allow time for the IRB to review the proposal and respond and thus cannot be the day the application is submitted or shortly thereafter. It cannot be the date of the IRB meeting, as this does not allow for response. An investigator may list "Upon IRB approval" as the starting date.
- Any research in which the principal investigator is a student must have a co-investigator who is a faculty or professional staff member.
- All researchers/investigators must have completed the FMU-designated human subjects Assurance Training Modules prior to submitting for IRB review.
- All items must be filled out. If Not Applicable to your study, write "NA".
- If a cooperative research project has multiple sites attach additional page(s) as needed to list sites.
- The completed IRB submission is given to the primary investigator's College Representative who forwards it to the IRB office after all documents are checked and the submission is confirmed as complete.
- Check to determine whether any Protected Health Information (PHI) is included in the study. This is information taken from patient records of any kind that are part of a HIPAA covered entity. Information that is gathered directly from subjects is not PHI even though you may ask for information from the subject that is in the patient record.

The principal investigator is also responsible for submitting an FMU-IRB Continuation/Renewal/Revision of Approved Studies Form (see Appendix E) if he/she is seeking an extension of the IRB approval of the study or needs to make revisions to an already approved study.

- Researchers are reminded that IRB approval is granted for one (1) year (or less, if the board determines that a study must be seen before the 12-month deadline) and that the IRB office must receive a completed Continuation/Renewal/Revision form no later than one month prior to the date of expiration of IRB approval.

- No research activities may continue past the date of expiration of the IRB approval (one year from the date of the approval letter) until the IRB has reviewed and approved the continuation.
- No revised protocol procedures may occur unless the IRB has approved the proposed changes. In addition, investigators should note that a change in procedure may alter the type of review needed for approval by the IRB. For example, a study that was approved at the Expedited Review level adds the collection of sensitive information from prisoners, thus the study would now require a Full Review.

Types of Review

Exempt Review

This level is reserved for research that represents no more than minimal risks to participants and does not involve special populations (such as the mentally retarded, some types of studies with children, prisoners, etc.). The purpose of this review is to determine if research is in keeping with the exempt categories as defined by regulation and thus exempt from Expedited or Full Review. Some examples of research that may be determined as exempt include:

- Research on the effectiveness of educational, classroom, and/or instructional strategies, provided that these strategies are familiar and non-intrusive in their implementation.
- Research using educational tests (cognitive, diagnostic, aptitude, achievement) if subject's identities are thoroughly protected.
- Research using survey procedures or interview procedures (not on minors) where subject's identities are thoroughly protected and their answers do not subject them to criminal and/or civil liability.
- Research involving the collection or study of existing data, documents, specimens, or other products, if these sources are publicly available.
- Research involving non-public data archives such as medical, psychological, or other clinical records if the dataset used is a de-identified data set as defined by HIPAA. Specifically, a de-identified data set is one which does not include any of the following pieces of information: names, all geographic subdivisions smaller than a state, all elements of dates (except years) related to any date such as birth date, admission date, discharge date, and so on, any reference to ages greater than 89 except to indicate that the age is 90 or greater, telephone numbers, fax numbers, e-mail addresses, social security numbers, medical record numbers, health plan identifiers, account numbers, certificate or license numbers, vehicle identifiers and serial numbers, license plate numbers, device identifiers and serial numbers, URLs, Internet protocol (IP) numbers, any biometric identifiers including fingerprints and voiceprints, full face photographs or other comparable images, and any other unique identifying number, characteristic, or code. The primary goal of these restrictions is to remove all identifiers that would allow the dataset to be identified in any way with any specific individual without their express consent.
- Datasets, which include some of the HIPAA defined identifying information detailed above, with a "very small" risk of the information being used to identify an individual. This

"very small" risk must be documented by a "person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable." The credentials of the individual providing the documentation must be presented along with the documentation.

It should be noted that only the chair or director of the IRB may determine that a study is exempt from Expedited or Full Review. Any member of the IRB reviewing a study at the College Level may consult with the Chair of the IRB if needed to get guidance on the type of review needed.

Expedited Review

This category is reserved for studies that do not meet the requirements for a College Level Review, but also do not represent more than a minimal risk to the clients involved. These studies may include:

- Studies with protected populations that involve only minimal risk and do not meet any of the specific exclusions for Exempt Review.
- Studies with surveying or interviewing of minors, or involving the observation of the behavior of minors where the researcher participates in the behavior being observed.
- Surveys that request information that potentially expose the informant to criminal or civil liability or are extremely personal in nature in which the likelihood of associating the individual with the response(s) is very small.
- Studies that expose normal populations to levels of physical or emotional stress which are somewhat greater than normal life or routine procedures, but which do not represent significant risks.
- Voice or video recordings made for research purposes, such as investigations of speech defects.
- Moderate exercise by healthy volunteers.
- Research on individual or group behavior characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- Research on drugs or devices for which an investigational device exemption is not required. For example: An audio tape on which subjects are asked to speak common words for the purpose of measuring voice timber would qualify for Expedited Review. A tape of a therapy session with a patient would not qualify for Expedited Review. Although the research involved an audio tape, the sensitive nature of the contents would require a Full Review.

Additionally, Expedited Review may be used when there are minor changes in previously approved research during the period (one year or less) for which approval is authorized.

The IRB is responsible for determining what does or does not meet the criteria for Expedited Review. Expedited Review may be carried out by the IRB Chair and by one or more reviewers designated by the Chair from among members of the IRB. When conducting an Expedited Review, IRB members may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after a full IRB review has been conducted. All IRB

members must be advised of research proposals that have been approved using expedited procedures at the next regularly scheduled meeting.

Full Review

Full review by the entire IRB panel is reserved for studies that have potential risk to human subjects. This may include but is not limited to:

- Research that involves the administration of drugs or other substances to subjects,
- Research involving pregnant women and/or fetuses in utero.
- Research involving subjects with life-threatening physical conditions.
- Research involving physically intrusive procedures.
- Research which previous experience (by the particular investigator or other investigators) has been shown to create a potential of risk to subjects.
- Research that may result in a significant level of psychological or physical stress.
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use) when there is a possibility that the subject could be identified.
- Research involving prisoners.
- Research that places protected populations (such as children, mentally retarded individuals, mentally ill individuals, patients with medical disorders) at more than minimal risk.
- Research involving waivers of any HIPAA regulations.

Types of IRB Actions

As a part of the Full Review procedure, the IRB shall review and have the authority to approve, tentatively approve pending receipt of additional information, or disapprove the subject research according to the following.

Approve

The protocol is approved as submitted.

Pending

A protocol is considered pending when problems are identified in the protocol. These problems frequently fall into two categories: 1) the investigator needs to clarify an aspect of the study, provide additional information, or discuss at great length the potential risks and benefits the study presents, or 2) minor changes need to be made to the informed consent document(s) or the research protocol. In these cases, approval may be given after the investigator rewrites the protocol and/or informed consent and/or submits to the Chair a written response to the IRB's questions and concerns. The Chair may then poll IRB members to receive final approval, as appropriate or can approve the changes as submitted.

In some instances, the Board may request that an investigator resubmit the revised

protocol for review by the full Board.

Disapprove

The IRB will disapprove the proposed research if it places the subjects at risks that outweigh the benefit or value of the knowledge to be gained, or it raises such ethical questions as to be unacceptable. A research activity may be disapproved only after a full IRB review has been conducted.

In each of the above cases, the IRB shall notify the principal investigator of the results of its action in writing.

Suspension or Termination of Research

The IRB shall have authority to suspend or terminate research that is not being conducted in accordance with the IRB's requirements, other institutional and federal requirements, or has been associated with any serious harm to subjects. Concerns regarding the conduct of research must be reported immediately to the Chair of the IRB by any individual having such knowledge. Any suspension or termination of research must include a statement of the IRB's action and the Chair must report its decision promptly to the principal investigator, the Office of Grants and Sponsored Programs, and the funding agency, in the case of a sponsored project.

Cooperative Research

Cooperative research projects are those that involve more than one institution (non-FMU hospital, public school district, DCF, etc.) and can be designed to be both multi-site and multi-protocol in nature. In the conduct of such projects, each participating institution is responsible for safeguarding the rights and welfare of human subjects and complying with all regulations.

Institutional Approval

In cases where the research project will be housed and conducted at another institution with participation by FMU faculty, staff, or research participants, it is required that documentation of the primary institution's IRB approval and a copy of the research protocol and consent forms be obtained and made part of the FMU IRB records. The proposed research project must then go through an additional review by and receive approval from FMU's IRB. All cooperative research projects involving FMU faculty, staff, or research participants, whether conducted at FMU or off-site, must have FMU IRB approval.

Assurances

It is the responsibility of the lead institution to file the required assurances and certifications with the Office of Human Research Protections (OHRP). All assurances

and certifications will be handled by the Office of Grants and Sponsored Programs.
Refer to Certification of Records section for further information.

Continuation/Renewal/Revision of Research Protocol

Continuation

Research can be approved by the IRB for no more than one year. A protocol may be reviewed more frequently if the degree of risk warrants. Research cannot continue beyond the one year period without IRB approval. It is the researcher's responsibility to secure this approval allowing adequate time for the process. Any correspondence from the IRB regarding continuation/renewal will be to the email, post office address, or intercampus mail address provided in the original submission. Primary investigators are encouraged to notify the IRB if their contact information changes during the study's implementation.

In order to allow for review and approval of a continuation request, investigators are asked to submit the continuation/renewal form (see Appendix E) and all appropriate documentation by no later one month before the expiration of the protocol's approval. Investigators are asked to check with center representatives for the procedure to submit request for continuation/renewal or revision.

Revision

If the investigator, during the course of conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of subjects), the principal investigator will notify the IRB Chair immediately, and in the case of funded research, the Office of Grants and Sponsored Programs. The Chair will determine the need for additional review, the type of review-full or expedited-and notify the IRB members.

It is important to note that: 1) that the PI must submit in writing any changes he/or she intends to make to the study to the IRB office, 2) that no changes can be implemented until the Chair and/or the IRB review and approve the changes, and that 3) failure to do so may result in the protocol's suspension and/or termination.

Continuation/Renewal/Revision of approved studies is commenced by the primary investigator completing the FMU-IRB Submission Form for Continuation/Renewal/Revision of Approved Studies (see Appendix E) and attaching all necessary documents.

Conflict of Interest

As documented previously in this manual, IRB members who may have a perceived conflict of interest with a study under review will excuse themselves from discussions related to the study. In addition, the university IRB is responsible for examining any possible conflict of interests investigators may have as they relate to human subjects. The FMU-IRB New Protocol Submission Form (see Appendix A) asks the primary investigator or any co-investigators to disclose any potential conflict of interest. It is also

the responsibility of investigators to provide such information in consent forms as this information may affect a subject's decision to be a participant in the study.

Adverse Events

Any adverse events must be reported to the IRB via the Serious Adverse/Sentinel Event Report within 72 hours (see Appendix H). The PI must also report the adverse event to a study sponsor/funding agency and all applicable regulatory agencies within 10 business days.

Chapter 4: Federal Privacy Legislation

HIPAA

Introduction

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is intended to protect the privacy of personal health information.

Researchers are encouraged to review information regarding HIPAA at the National Institutes of Health (<http://privacyruleandresearch.nih.gov/>) website.

Waivers of Authorization Under HIPAA

Due to the passage of HIPAA, there are special situations that apply to research that use Protected Health Information (PHI) without patient authorization. While HIPAA allows for certain waivers or alterations, FMU has taken a more restrictive approach in the interests of fully insuring patient privacy.

The IRB will not approve any research that does not follow the normal subject authorization process unless such a waiver is approved by the privacy officer of the covered entity and the IRB subsequently specifically approves such a waiver. Except in the case of preparatory research (see following section), such projects will be approved by submission of the standard IRB protocol along with a letter of approval from the privacy officer at each involved covered entity. In cases where research is conducted at another institution, the approval of the Privacy Board and/or privacy officer of that institution must be included in the proposal.

Please note that the IRB regards patient privacy and confidentiality as the utmost importance. Therefore, waivers will not be granted frequently. The IRB Center Representatives are available to help and encourage researchers to consider alternative designs which use de-identified data sets, limited dataset agreements, or direct patient authorizations as methods of allowing research with little or no risk to patient confidentiality. The fact that such alternatives are more costly, cumbersome, slower, or inefficient is not a reason to grant a waiver.

Preparatory Research Activities Under HIPAA

Conducted by members of the covered entity. Under preparatory research activities, HIPAA allows employees of any of the FMU covered entities to conduct preparatory research activity. Such activity involves the examination of files and collection of data to determine how many subjects might be included in a given study (such as patients with a certain diagnosis or undergoing a certain procedure) and the characteristics of those subjects (such as age, gender, ethnic background, etc.) In addition, HIPAA allows staff of the covered entity to contact prospective research subjects. These activities are allowed only after approval of the IRB on the "Review Preparatory to Research

(Covered Entity Workforce) Form” form (See Appendix F). This form would normally be reviewed at the college/center level after approval by the privacy officer of the specific covered entity. However, no research may be conducted until there has been approval for the research project by the IRB using the procedures described in this manual.

Information conveyed to individuals outside the covered entity. HIPAA allows disclosure to an individual outside of the IRB as part of preparatory research activities. The IRB does not normally allow disclosure to an outside entity of any specific information which would allow that outside organization to contact or identify the client /subject prior to IRB approval of the research protocol. Covered entities may reveal information that was collected under an approval to do preparatory research, provided that the information is aggregated to the outside entity, reporting such information as frequency or number of people with a given diagnosis, average age, average education, gender distribution, ethnic distribution, prior to IRB approval of the research protocol. However, data such as name, address, phone number, or social security number may not be disclosed prior to IRB approval of the research protocol unless a waiver is granted (see following section).

Preparatory research conducted by individuals outside the covered entity. Under most conditions, individuals outside the covered entity are not allowed to collect preparatory data from client files or to receive identified data without the consent of the client. The exception to this is the granting of a waiver by the IRB or other duly constituted privacy board. Such waivers are granted only when there is no other possible way to conduct the preparatory research without granting the waiver. The fact that such alternatives are more costly, cumbersome, slower, or inefficient is not normally a reason to grant a waiver. In cases where the outside individual or organizations feels that a waiver is appropriate, the IRB preparatory research waiver form must be filled out, approved by the clinical director of the appropriate covered entity, and then submitted to the IRB. Such waivers will be reviewed by the full IRB board and require approval of the Board as a whole. If such a waiver is granted, the outside agency may not take any identified data from the covered entity nor can such an entity contact prospective subjects until a full research proposal has been reviewed and approved by the IRB.

Review Preparatory to Research (Covered Entity Workforce) Form (see Appendix F)
IRB Waiver Request Form (Preparatory Research-Non-covered Entity Workforce) Form (see Appendix G)

Research on Decedent’s PHI

HIPAA allows research on the PHI of decedents without authorization from a representative of the decedent; however, such studies must first be approved by the IRB. As part of the research protocol, the researcher must indicate that the study (or an aspect of the study) is to research the PHI of decedents, justify why this is necessary, and the class of individuals to be studied (all deaths, deaths from heart disease, deaths where cause is unknown, deaths in January, etc.) Appropriate means for protecting the

privacy of the decedent and relatives (where appropriate) also be documented. Such review must be approved by the clinical director at each FMU clinic involved.

Access to PHI for Research Subjects

During a clinical study, it may be necessary in some cases to restrict a patient's access to certain information within their records. Such restrictions should be as minimal as possible while insuring the validity of the clinical trial. In cases where restrictions will take place, the Informed Consent Form must include an additional section labeled "Restriction of Access to Records". In this section, the researcher must detail the extent of the restriction, the time period of the restriction, and at what point in time the restriction will be lifted.

Elements of an Authorization

The university IRB has determined that authorization to use or disclose an individual's PHI for research shall be incorporated within the informed consent form. The consent must contain the following specific core elements and required statements:

Authorization Core Elements:

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the consent, a description of the representative's authority to act for the individual must also be provided.

Authorization Required Statements:

- A statement of the individual's right to revoke his/her authorization and how to do so, and if applicable, the exceptions to the right to revoke his/her authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on authorization, including research-related treatment and consequences of refusing to sign the authorization, if applicable.
- A statement of the potential risk that PHI will be re-disclosed by the recipient.

This may be a general statement that the Privacy Rule [HIPAA] may no longer protect health information disclosed to the recipient.

FERPA

The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."

- Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies.
- Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement within the record setting forth his or her view about the contested information.
- Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):
 - School officials with legitimate educational interest;
 - Other schools to which a student is transferring;
 - Specified officials for audit or evaluation purposes;
 - Appropriate parties in connection with financial aid to a student;
 - Organizations conducting certain studies for or on behalf of the school;
 - Accrediting organizations;
 - To comply with a judicial order or lawfully issued subpoena;
 - Appropriate officials in cases of health and safety emergencies; and

- State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school.

The protection of such records may impact how researchers gain information from student records, solicit subjects, and other elements of a protocol's methods and procedures. Researchers are encouraged to review information regarding FERPA at the Department of Education's website (<http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html>).

PPRA

The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED) including public schools. PPRA is intended to protect the rights of parents and students in two ways:

- It seeks to ensure that schools and contractors make instructional materials available for inspection by parents if those materials will be used in connection with an ED-funded survey, analysis, or evaluation in which their children participate; and
- It seeks to ensure that schools and contractors obtain written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that reveals information concerning:
 1. Political affiliations;
 2. Mental and psychological problems potentially embarrassing to the student and his/her family;
 3. Sex behavior and attitudes;
 4. Illegal, anti-social, self-incriminating and demeaning behavior;
 5. Critical appraisals of other individuals with whom respondents have close family relationships;
 6. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or

7. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

Researchers are encouraged to visit the Department of Education's website at <http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html>

Chapter 5: Research with Special Populations

The federal government has extensively regulated and provided additional safeguards with respect to research, development, and related activities involving "special populations"; these include pregnant women and fetuses, prisoners, and children. The following are guidelines for the inclusion of these special populations as subjects in research. If faculty, staff, and students need additional information and/or clarification regarding special populations, they are to contact the IRB Chair, the Chair's designee, the IRB Administrator, or the Office of Grants and Sponsored Programs.

Pregnant Women and Fetuses

No research activities involving pregnant women and fetuses may be undertaken unless appropriate studies on animals and non-pregnant individuals have been completed. The purpose of the activity must be to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity. Individuals engaged in the research activity will have no part in 1) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and 2) determining the viability of the fetus at the termination of the pregnancy; and 3) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

1. Pregnant Women as Subjects

No pregnant woman may be involved as a subject in any research activity unless the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus is minimal. Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus. The father's informed consent need not be secured if the purpose of the activity is to meet the health needs of the mother; his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.

2. Fetuses in Utero as Subjects

No fetus in utero may be involved as a subject in any research activity unless the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent. The father's informed consent need not be secured if his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.

3. Fetuses ex utero, Including Nonviable Fetuses, as Subjects

Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in any research activity unless there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability. No nonviable fetus may be involved as a subject in any research activity unless vital functions of the fetus will not be artificially maintained; experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed; and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements included herein. Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape. Activities involving a dead fetus, macerated fecal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such activities.

Prisoners

Inasmuch as prisoners may be under constraints because of their incarceration that could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, additional safeguards for their protection must be adhered to. With respect to research involving prisoners, the IRB shall also meet the following specific requirements:

- A majority of the Board (exclusive of prison members) shall have no association with the prison(s) involved, apart from their membership on the Board
- At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB Board, only one Board need satisfy this requirement.

The following research involving prisoners is permitted:

Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

1. The institution has certified to DHHS that the IRB has approved the research, and
2. In the judgment of the agency, the research involves solely the following:
 - the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - the study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere);
 - research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) only after the Secretary of the DHHS has consulted with appropriate experts, and published in the Federal Register his or her intent to approve such research; or research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject.

In cases in which studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the research may proceed only after the Secretary of the DHHS has consulted with appropriate experts, and published in the Federal Register his/her intent to approve such research.

It is important to reiterate that investigators cannot use prisoners as a sample of convenience and that any study involving prisoners will be reviewed carefully for coerciveness and to be sure that study risks inherent to this population have been minimized.

Children

Research involving children is permitted in the following instances when/if the IRB finds that no greater than minimal risk to children is presented, and adequate provisions are made for soliciting the assent of the children and the permission of parents or guardians, as outlined below.

1. The IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds the risk is justified by the anticipated benefit to the subjects; the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
2. Adequate provisions are made for soliciting assent of the children and

permission of their parents or guardians, as outlined below.

3. The IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:
 - the risk represents a minor increase over minimal risk;
 - the intervention or procedure presents experiences that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
 - the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for understanding or amelioration of the subjects' disorder or condition; and

Wards

Children who are wards of the state of any other agency, institution, or entity can be included in the research only if such research is: related to their status as wards, or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the IRB approves the research, it shall require the appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in a manner that assumes the duties and responsibilities of a parent (*in loco parentis*). One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator(s), or the guardian organization.

Requirements for Parental/Guardian Permission and for Assent by Children

The IRB requires that adequate provisions are made for soliciting the permission of each child's parents or guardians prior to the solicitation of the child. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient if the research does not involve greater than minimal risk, or does involve greater than minimal risk, but presents the prospect of direct benefit to the individual subjects. If the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizing knowledge about the subject's disorder or condition, the IRB will require both parents' permission. Exceptions would include: 1) one parent is deceased, unknown, incompetent, or not reasonably available, or 2) when one parent has legal responsibility for the care and custody of the child. Permission by parents or guardians shall be documented in accordance with and

to the extent required under the Informed Consent section of this manual.

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when, in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is limited to the point that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

When the IRB determines that assent (from subjects 7-17 years old) is required, it shall also determine whether and how assent must be documented.

Workers/Employees

Research conducted on workers or employees should take into consideration the potential status of these individuals as vulnerable subjects. Concerns such as coercion (particularly when the investigator is also an employer or supervisor), confidentiality, privacy, and permission by an employer to work with his/her employees must be evaluated and minimized.

Students

The relationship of teacher and student is one that automatically questions the voluntary nature of a student's participation. Instructors who are researchers must be sensitive to potential coercion and must design protocols in consideration of this fact. The IRB does permit giving extra credit/credit to students who participate in research only when alternative means of obtaining credit are available to students who do not wish to volunteer for research. The extra credit/credit must be calculated and announced to the class, preferably within the syllabus, in advance. Additionally, the non-research extra credit activities must be comparable in time/commitment as the research activities. The Board will likely consider non-research activities that are not comparable to the proposed research activities as coercive. In order to maintain the voluntary nature of participation in research, students should also be able to elect to leave the research activity at any time and complete one of the other non-research extra credit activities to be able to still earn the credit. Protocols should be designed so that subject recruitment is not conducted by the instructor/researcher. Instead, a colleague should be called upon to explain the study and solicit students, and then allow for adequate time for the students to decide if they would like to participate in the research. Beyond this, informed consent procedures for students should adhere to FMU guidelines and the Common Rule in all aspects.

Appendix A
FMU-IRB New Protocol Submission Form

**Florida Memorial University
Institutional Review Board for Research with Human Subjects (IRB)
New Protocol Submission Form**

To be completed by Center/College Representative	
Date Received:	FMU Center/College:
Center/College Representative:	
Protocol Qualifies for:	
Full Review <input type="checkbox"/> Expedited Review <input type="checkbox"/> College/Center Level Review <input type="checkbox"/>	
To be assigned by Office of Grants and Sponsored Programs	
Protocol Number:	

Instructions: In order to comply with federal regulations as well as to conform with guidelines of the university's Institutional Review Board (IRB), the principal investigator is required to complete all of the following items contained in the Submission Form and the IRB Protocol. Upon completion of all information, the principal investigator must submit the original Submission Form and one copy of the IRB Protocol, including all consent forms and research instruments (questionnaires, interviews, etc.) to the appropriate IRB College/Center Representative for review and action. Once reviewed, if the protocol requires full review, the College/Center Representative will direct the principal investigator to submit the original Submission Form along with 13 copies of the Submission Form and all supporting materials to the Office of Grants and Sponsored Programs. In addition, 13 copies of all research instruments (questionnaires, interviews, etc.) must be submitted. The completed package must be received by the Office of Grants and Sponsored Programs by the last business day of the month prior to the next scheduled IRB meeting. The Office of Grants and Sponsored Programs' Web site should be consulted for IRB meeting dates. Incomplete forms may delay review by the IRB. For further information, refer to the *Procedure Manual for Research with Human Subjects.*

I. General Information

Project Title _____

Proposed Start Date _____

Proposed Duration of Research _____

Performance Site(s) _____

Principal Investigator Information

Name		Relationship to FMU: Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/>
Office Mailing Address (Home Address if Student):		
Office Phone <small>(Home Phone if Student):</small>	Alternate Phone	FMU Center/College:
Email Address:		
		Fax:

Co-Investigators' Information (including faculty advisers):

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name			
Address			
Contact Phone Number			
Email Address			

Has the Primary Investigator completed the FMU-designated human subjects research training (Assurance Training Modules)? Yes No

If you answered yes, please include a copy of your training certificates of all three modules. If you answered no to this question, please note that no IRB action may take place until proof of completion of training is provided.

II. Funding Information (if applicable)

Are you applying for funding, or have you received funding? Yes No

If yes was indicated, please provide the following information:

- A. Source of Funding _____
- B. Project Title (if different from above) _____
- C. Principal Investigator (if different from above) _____
- D. Type of Application: Grant _____ Subcontract _____ Contract _____ Fellowship _____
- E. Date of Submission _____
- F. Grant Amount _____

Does the primary investigator or any co-investigators have a significant financial interest (i.e., salary/payments, equity interests, intellectual property rights) in relation to this study? Yes No

If you answered yes, please be sure to include within the description section of all applicable consent forms the following statement: "The principal investigator and/or co-investigator(s) of this research study have a significant financial interest as it relates to this study."

III. Cooperative Research

Cooperative research projects are those that involve more than one institution and can be designed to be both multi-site and multi-protocol in nature. Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations. If this proposal has been submitted to another Institutional Review Board (or authorizing individual/entity), please provide the following:

Name of Institution _____
 Date of Review _____ Contact Person _____
 IRB Recommendation _____

IV. Subject/patient Information

A. Types of Subjects/Patients (check all that apply and provide number of subjects):								
Subject Group	Fetus in Utero/ non-viable fetuses/ abortuses	Newborns or Infants	Children (aged 2-7)	Children (age 8-12)	Adolescents (aged 13-17)	Adults (18+)	Pregnant Women	Adults with Guardians
Check if in Study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
# of Subjects								
Do any of the checked subjects belong to a special population (e.g., prisoners, mentally disabled)? Yes <input type="checkbox"/> No <input type="checkbox"/>								
If you indicated Yes, please specify:								
<input type="checkbox"/> Prisoners								
<input type="checkbox"/> Mentally disabled								
<input type="checkbox"/> Mentally ill								
<input type="checkbox"/> Other (specify): _____								
If you answered yes, please specify in detail the nature of the special population(s)?								
Will the study require translation of consent forms? Yes <input type="checkbox"/> No <input type="checkbox"/>								
If you answered yes, please specify the language(s) that the consent forms will be translated into:								

B. Other (Check all that apply):
Use of investigational drugs or devices <input type="checkbox"/>
Information to be collected may require special sensitivity <input type="checkbox"/> (e.g. substance abuse, sexual behavior) Please specify:

C. Total Number of Subjects/Patients _____
D. Approximate time commitment for each subject/patient _____
E. Compensation to subjects/patients: Yes <input type="checkbox"/> No <input type="checkbox"/>
F. If you answered yes to letter E, please indicate the form of Compensation (e.g. cash, taxi fare, meals, gifts) _____ Amount (value) _____ (per person)

G. Does this study involve the use of protected health information (PHI) from client charts or other records? Yes <input type="checkbox"/> No <input type="checkbox"/>
--

If Yes, will consent be obtained from the client for all PHI collected? Yes <input type="checkbox"/> No <input type="checkbox"/>
If consent is not obtained, which of the following applies?
<input type="checkbox"/> The data will be collected in a fully de-identified data set.
<input type="checkbox"/> The data will be collected as part of a limited dataset agreement.
<input type="checkbox"/> The data will be collected under a waiver from a duly constituted privacy board. (Please attach a copy of the waiver to this form.)

V. Submission Checklist (to be completed by primary investigator)

- Research Protocol
- Informed Consent Form Checklists (one checklist per consent form)
- Consent Form(s)
- Data Collection Instruments
- Cooperative Research IRB/Administration Approval Letter(s)
- If this is a Health Professions Division (HPD) study, the appropriate approvals are attached and review by the HPD Research Committee has occurred.
- Certificate of Human Subjects Research Training

VI. Principal Investigator Assurance and Obligations

I certify that all information provided in this submission (including information provided in the research protocol and supporting documents) is a complete and accurate description of the proposed study.

I agree to the following:

- This study will be conducted in the manner described in this submission. No changes to this study will be implemented until a revision form has been submitted and approved by the IRB.
- This study will be conducted during the one year approved by the IRB (or less as stipulated by the IRB). If the study will exceed the approval period, I will submit in a timely manner a Continuation/Renewal/Revision form. I understand that the study may not continue past an approval period.
- When applicable, I will provide a copy of the signed informed consent form to the subject or patient.
- I will retain all signed informed consent documents for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date the study is concluded.
- I will report in writing any serious adverse events to the IRB within 10 business days.
- I will provide participants with any significant new information obtained during the course of the study.
- If my study has been approved at the Expedited or Full Review levels, I will report to the IRB when this study has closed.

Principal Investigator's Signature: _____ Date: _____

Appendix B
Research Protocol

Outline of Research Protocol

Every IRB application is to be accompanied by a detailed research protocol. This protocol must follow the outline below. If an area is not applicable, the heading should be listed followed by “Not applicable” or “None” to insure that the area was considered by the investigator.

Description of Study

Protocol Title

The protocol title is the same as the project title provided on the FMU-IRB submission form and on all consent forms.

Principal Investigator and Co-Investigator

List the complete name, address, telephone and fax numbers, and email address of the Principal Investigator. List the address, contact number, and email address of all Co-Investigators. Students must include faculty adviser/thesis chair as a co-investigator.

Funding/Sponsor of the Study

List all of the funding sources/sponsors of the study. If there is no external funding, please indicate with “None.”

Purpose and Potential Benefits

This section is intended for a description of the main goals and justification for the study as well as a brief literature or historical overview pertinent to the study. Investigators should summarize the background, rationale, nature, and significance of the proposed research. It is helpful to discuss the results of previous related research. The investigator should discuss any potential benefits of the study as these relate to professional/scientific knowledge.

Location of Study

All sites where data will be gathered are listed within this section. If this includes non-FMU sites, an agreement from those sites for the conduct of the study must be attached. Include the name, degree(s), title, employing institution, and complete address of the investigator(s) at each site. If the study is Internet based, the investigator should describe where data will be collected (individuals logging in from home, subjects coming to a physical site, etc.).

Dates of Study

Start Date: Actual start date may not be before approval by the IRB, and any start date must allow for IRB review and response. You may list “Upon IRB approval” if the study is to begin immediately after approval is obtained. This date matches the information provided on the FMU-IRB New Protocol Submission Form.

End Date: Anticipated end date. (Note that all studies that take more than one year must be renewed annually via the Continuation/Renewal Revision Form).

Subjects

This section is intended for investigators to provide details about all the proposed subjects in the study.

Sample Size and Composition

Included within this section are descriptions of the number of subjects, age ranges, gender, ethnicities, primary language(s) of subjects (if other than English), and the presence of any conditions that would make this a protected population (such as pregnancy, mental health disorder, illness, prisoner, decisionally impaired, etc.). Justification for use of any special/vulnerable subject population should be included.

Subject Selection, Recruitment, and Eligibility Requirements

This section must include a detailed description of how subjects will be recruited, how they will be screened, and what eligibility criteria will be used. If subjects come from any entity that is covered by HIPAA, particular attention should be paid to methods that will be used to insure patient privacy.

Any media, including flyers, brochures, or other advertisements used to recruit human subject participation in a research study, must be submitted to the IRB for review and approval and must be included as part of the IRB submission package.

This section must also provide a detailed description of the proposed informed consent process, with particular attention to the minimization of coercion and discussion of how the investigator will provide an opportunity for the prospective subject, or the legally authorized representative, to consider whether or not to participate in the study. This section should also include the circumstances surrounding language difficulties/translators, obtaining assent from minors, and using witnesses.

Methods and Procedures

This section should include all details as to what will happen to subjects throughout the study and in what order. If there is more than one study group, details should be given separately for each group. All tests or procedures should be indicated (and described more fully) in the next section. The time periods involved for all work should be provided. Provisions for managing adverse reactions are to be included. Any compensation to subjects or extra costs to subjects should be discussed. Any compensation for injured research subjects should be discussed.

Measures and Administration

This should include a paragraph or more on all tests or procedures used. If these are paper and pencil measures, a copy should be attached. A copy of all surveys or questionnaires must also be described and attached. If the procedures are not "paper and pencil," they should be described in detail so they can be understood by an intelligent layperson.

Risks to Subjects

This section is intended for possible risks to the client. All studies must address the issue of possible loss of subject confidentiality, while other risks are unique to the specific study. Each risk should be addressed in the following format individually, with as many paragraphs as there are risks to the study.

- Risk: List each risk individually
- Likelihood: Usually classified as minimal, moderate, or high.
- Magnitude/Duration
- Minimization: These are procedures undertaken to minimize the risk that this specific risk poses.

Investigators should be sure to discuss all potential risks, discomforts, hazards, or inconveniences of the research study. Some possible risks include physical pain or discomfort, psychological or emotional harm, invasion of privacy, and loss of time or pay. Some studies, due to the nature of the population, present risks to a community or group of individuals. These risks must also be addressed.

Benefits to Subjects

This section is intended for all direct benefits of the study to participants. This does not usually include “helping research” or other generalities, nor does it include compensation for participation. Some examples of benefits include: receiving free treatment, receiving a list of reputable local services, tutoring skills, or an informed debriefing. The value of any such benefits should be listed as well. If there are no direct benefits to the participants, this should also be indicated.

Risk/Benefit Ratio

An overall analysis of the risks of the study to the benefits received by the subject as well as the general benefits of the study itself to science research should be discussed. The review of risks to benefits is a key element in IRB review.

Consent Forms

A list of the consent forms used in the study and who will sign and present them should be included. A copy of all consent forms on letterhead (all pages) in final form must be attached. If the study requires translated informed consent forms, the primary investigator is encouraged to wait for notification from the IRB that the English version of the consent is acceptable before translating the consent form(s). After the consent forms are translated, they must be submitted, on letterhead, along with certification of the translation to receive final approval to commence the study (if a translation service other than the FMU recommended one was used).

PHI Use

If the study involves the gathering of data from patient/student records, this section must specify the exact data which are gathered (e.g., age, height, blood pressure, IQ score, diagnosis, depression rating, number of treatments, etc.). If such data are gathered, this section also must indicate whether the data are gathered as part of a de-identified data

set, a limited data set, a result of patient authorization as part of the consent form, or waiver from a privacy board. If the dataset is based on a limited data set agreement, then that agreement along with the justification that establishes that confidentiality is protected must be placed here or attached. If there is a waiver from a privacy board, then that waiver must be attached.

Credentials/Qualifications of Researcher(s)

Biographical Sketch			
Name		Position Title (if student, indicate "Student")	
Education/Training (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
Institution and Location	Degree (if applicable)	Year(s)	Field of Study

Research and Professional Experience: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government, public advisory committee. Also, list, in chronological order, complete references to all publications during the past three years as well as earlier publications pertinent to this protocol. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **Note: For HPD studies, where this information has already been provided as part of the HPD submission, the investigator may state "see HPD submission form."**

Appendix C
Informed Consent Form Instructions
Frequently Asked Questions Regarding Informed Consent
Exceptions from Requirements for Informed Consent
Informed Consent Form Checklist

Informed Consent Form Instructions

General Considerations

One significant outcome of the Nuremberg medical trials was the establishment in 1947 of the Nuremberg Code, which set forth ten principles for conducting research involving human subjects. The first of those principles states, "the voluntary consent of the human subject is absolutely essential." Thus, no investigator may involve a human being as a subject in research, as defined in this procedure manual, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted by two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced (i.e. his or her consent is voluntary). Once informed consent is obtained, documentation to that effect shall follow the procedures outlined in this manual.

Additionally, the researcher should be aware that litigation against the University is always a possibility. From this perspective, even an ethical informed consent is not sufficient. Rather, we need an ethical informed consent which is legally valid and the legal validity of which can be demonstrated should such a need arise.

The researcher should also be aware that signed informed consent form documents must be retained for a minimum of three (3) years from the date the study is concluded (or longer depending on the requirements of certain funding agencies).

Types of Informed Consent Forms

There are four types of consent forms, as follows:

Adult/General Consent Form

Used for subjects 18 years and older who are capable of giving informed consent. This includes most adult subjects. In some cases, parents are participating in a study while their child is not. The Adult/General Consent Form would be the appropriate choice. If parents are giving consent for their child(ren) to participate in a study and agreeing to participate themselves at the same time, the Parent/Guardian Consent Form should be used.

Children Assent Form

For children between the ages of 7 and 12 years, an assent form is used which is written in a simpler format with language appropriate to the youngest child in this age range; however, it still contains the major required elements. For children under 7 years, the same information needs to be conveyed but may be done orally at the child's level of development. The oral explanation of the study to the child should be attested to by the parent on the Parent Consent Form when a written assent is not possible. Infants

and children unable to understand do not need to assent.

Adolescent Assent Form

Used when subjects are in the age range of 13 and 17 years. The Adolescent Assent Form is generally the same as for the adults except it is written in language appropriate to the youngest teenager to be included in the study. This form is used in conjunction with the Parent/Guardian Consent Form.

Parent or Guardian Consent Form

Anytime a subject under 18 is involved, consent must be obtained from the parent or guardian. This form is again similar to the Adult/General Form. However, rather than saying “you,” the subject is referred to as “your child.” This form would also contain information regarding any parental/guardian participation in the study. If the study requires a guardian of an adult to provide consent, it should read “your ward.”

Studies may need to use only one or several of these forms, depending on the groups involved in the research. For example, if different procedures are used for teachers and parents, use two different consent forms.

General Requirements for the Consent Form

All sections described below must be included in every consent form. The length or applicability to a given study may vary, but the sections must appear in the standard order listed on the example document layouts. This allows the IRB to see quickly that the researcher has considered all elements of the consent form.

- Every page of the consent form should be on Florida Memorial University letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable. All letterhead must be the original, not a copy. All proposed consent forms must be submitted on FMU letterhead as well. Please contact your College Representative for FMU letterhead.
- The consent form should be in language understandable to the subject or his or her legal representative. It must be written in a consistent voice: either first, second, or third person (not a combination). In general, the consent form should be in second person (“You are being asked to participate...”). The consent language of the child or adolescent assent should account for the ages of the subjects. For subjects who would better comprehend the consent form in their native language, the consent must be provided in a translated version.

- The university requires that translation of consent forms and data collection instruments (when these are going to be provided in a language other than English) be conducted by an individual/company that is certified to translate the consent form into the respective languages. Proof of certification must come with the translated consent forms. The university recommends, but does not mandate, that researchers use the services of Student Services International, Inc.

Student Services International, Inc
 2455 East Sunrise Boulevard, Suite 200
 Fort Lauderdale, FL 33304
 954-565-8505 ext 29
 fax 954-565-8718
www.talkinusa.com

- If the research is externally funded, the funding agency should be listed under funding source.
- The title of the study and the name, address, and telephone number of the investigator(s) follow immediately before funding source. The Principal Investigator's address and phone number, and the number of the IRB Office (305.623.4225) must appear on the consent form. If the principal investigator is a student, the address and phone number of his/her advisor(s)/clinical supervisor(s) must also appear on the form. If the research is conducted at a setting where contacting the researcher or the advisor might be difficult (such as when the research is done out of state or in a prison), a local contact who the subject can easily reach should also be listed.
- Informed consent should be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence.
- Language that states that research files could be audited by regulatory agencies when appropriate.
- When required by the IRB, one or more of the following elements shall be provided to each subject:
 - (a) Statement that procedure may involve unforeseeable risks to the subject;
 - (b) Description of circumstances under which the subject's participation may be terminated by the investigator without the subject's consent;
 - (c) Additional costs to the subject resulting from participation in the research;
 - (d) Approximate number of subjects involved in the study.

Frequently Asked Questions

- When are consent forms required?

Consent forms are required in all studies that collect information for or about human subjects except under the following conditions:

1. Research on a de-identified dataset (as previously defined)
2. Research on a limited dataset pursuant to a dataset agreement
3. Research or preliminary research authorized by a duly appointed privacy board
4. Research conducted using an anonymous survey to adults, where a statement about the voluntary nature of the survey is contained in the survey instructions

- Does the consent form always have to be signed?

In general, all consent forms must be signed and properly witnessed. A copy is to be given to the subject as well. The IRB may waive the requirement to obtain a signed consent form for some or all subjects if:

1. the only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality, and
2. the research presents no more than minimal risk and involves no procedures for which written consent is normally required. In cases where documentation is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. For example, there are some surveys where the likelihood of any risk is minimal (such as a questionnaire about food preferences) and where the only information identifying the client would be the signature on the consent form. In such cases, instead of a signature line, the researcher may add at the end of the standard consent form, "I understand that my completion of this survey (or questionnaire) implies my consent to participate in this study."

- Do I always have to use the FMU consent form format?

In general, the answer is yes; however, in cases where the study is being done in its entirety at another institution with a federally approved IRB, the researcher may request that he or she use the form of that institution. In such cases, the researcher must submit the alternate consent form along with approval from the other IRB. Such a request will be reviewed to see that the form meets FMU requirements although in a different format. In cases where the requirements are met, the alternate consent form may be used. In other cases, the IRB may suggest alterations to bring the form into compliance, or, if this is not possible, the use of two consent forms.

- How long should I keep signed informed consent forms?

Signed consent forms should be retained in a secure file for a minimum of three (3)

years from the date the study was concluded. You should note, however that some funding agencies require a longer period of time. For multi-site studies, the date of study completion may exceed the date you stop the study at your local site. The date you must use to account for the three years is the date ALL research related to the study concluded.

Exceptions from Requirements for Informed Consent

DHHS Exceptions

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents:

- The research involves no more than minimal risks
- The rights and welfare of subjects will not be adversely affected
- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- The research is to be conducted for the purpose of demonstrating or evaluating federal, state, or local service programs that are not research programs, etc.

Short Form Documentation

In most cases, the standard consent forms described under Types of Informed Consent Forms should be used; however, in some cases, the IRB may authorize the use of a short form that states that the elements of informed consent have been obtained from the subject. When using the short form the following conditions must be met (The written summary of what is to be said receives prior approval of the IRB.):

- The witness must be present at the oral presentation
- The short form is signed by the subject or his/her representative
- The witness signs both the short form and the written summary is given to the person signing the form
- A copy of both the short form is provided along with the written summary.

**Florida Memorial University
IRB - Informed Consent Form Checklist**

This form must be completed by the researcher and submitted with the research protocol and informed consent form. Failure to do so will cause review of your protocol to be deferred.

Informed consent is one of the primary ethical requirements for research with human subjects; it reflects the basic principle of respect for persons. No principal investigator may involve a human being as a subject in research, as defined in the Florida Memorial University Institutional Review Board Procedure Manual for Research with Human Subjects, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted on two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced (i.e. his or her consent is voluntary).

The checklist below is provided to ensure that each of the following components is included in your Informed Consent form. Please check N/A next to those items that are not applicable to the protocol being submitted.

This checklist is intended for the following consent form: _____

Included	N/A	Component
<input type="checkbox"/>	<input type="checkbox"/>	The Informed Consent form is written in a language understandable to the subject or his/her legal representative.
<input type="checkbox"/>	<input type="checkbox"/>	The Informed Consent form is written in a consistent voice, preferably second with the exception of the Voluntary Consent section, which is written in the first person.
<input type="checkbox"/>	<input type="checkbox"/>	Each page of the Informed Consent form is on original Florida Memorial University letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable.
<input type="checkbox"/>	<input type="checkbox"/>	If the research is externally funded, the funding agency is listed under funding source.
<input type="checkbox"/>	<input type="checkbox"/>	The title of the study and the name, address, and telephone number of the investigator(s) are listed.
<input type="checkbox"/>	<input type="checkbox"/>	If the principal investigator is a student, the address and phone number of his/her advisor(s)/clinical supervisor(s) are listed.
<input type="checkbox"/>	<input type="checkbox"/>	The phone number for the IRB Office (305.623.4225) is listed.
<input type="checkbox"/>	<input type="checkbox"/>	A statement that the study involves research and an explanation of the purpose of the research is included.
<input type="checkbox"/>	<input type="checkbox"/>	A concrete description of the study procedures, including the amount of time subjects are being asked to contribute and the nature of the questions or data to be collected, is included. Any procedures which are experimental are identified and any alternative procedures disclosed. Information about financial agreements with the investigators must be discussed.

<input type="checkbox"/>	<input type="checkbox"/>	A description of any risks and possible discomforts to the subjects, if any, is included.
<input type="checkbox"/>	<input type="checkbox"/>	A description of any benefits to the subjects is included. If no benefits are expected, this is stated.
<input type="checkbox"/>	<input type="checkbox"/>	If subjects will be compensated for their participation, a statement has been included addressing this.
<input type="checkbox"/>	<input type="checkbox"/>	A statement describing the extent to which confidentiality will be maintained is included in addition to a clause that states that all information obtained is strictly confidential unless disclosure is required by law.
<input type="checkbox"/>	<input type="checkbox"/>	As a part of the confidentiality section, a statement that the FMU-IRB and other regulatory agencies may review research records.
<input type="checkbox"/>	<input type="checkbox"/>	A statement regarding the use, or non-use, of Protected Health Information (PHI) if the study involves PHI.
<input type="checkbox"/>	<input type="checkbox"/>	A statement regarding the use, or non-use, of information from student records if the study involves student records.
<input type="checkbox"/>	<input type="checkbox"/>	A statement that participation is voluntary, that refusal to join the study or to leave the study involves no penalty, and that the subject may discontinue participation at any time. This statement must be followed by an explanation of how data collected will be managed if a participant decides to leave (e.g., destroyed at any time, except in situations that violate state and/or federal laws and regulations, kept until the conclusion of the study, etc.).
<input type="checkbox"/>	<input type="checkbox"/>	A statement indicating who the subject can contact for any questions about the study.
<input type="checkbox"/>	<input type="checkbox"/>	The Informed Consent contains no language through which the subject is made to waive any of his/her legal rights or which releases the investigator, the sponsor, or the institution from liability for negligence.
<input type="checkbox"/>	<input type="checkbox"/>	The entire paragraph under Section VI-Voluntary Consent on the Informed Consent form appears in boldface and reads " I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate. All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study they will be answered by (fill in name). (If applicable: I also voluntarily agree to the release of my PHI as described in this document.) A copy of this form has been given to me. This consent ends at the conclusion of this study. "
<input type="checkbox"/>	<input type="checkbox"/>	Spaces for the subject's signature, the signature of a witness, and the dates are provided. Spaces are also provided for the signature of an authorized representative, date, and the basis for that representation, if applicable.
<input type="checkbox"/>	<input type="checkbox"/>	An assent form is included for subjects 7-17 years of age. This may be either a child assent, an adolescent assent, or both (depending on the age range of subjects).

<input type="checkbox"/>	<input type="checkbox"/>	Flyers, brochures, advertisements, or other recruitment materials are attached.
<input type="checkbox"/>	<input type="checkbox"/>	If the language of the Informed Consent Form is other than English, a certified copy of the Informed Consent Form in that language is included or the investigator may wait until notified by the IRB to have the consent form translated.
<input type="checkbox"/>	<input type="checkbox"/>	All consent pages are numbered. All non-final pages contain a blank space for initials and date.

Appendix D
Sample Informed Consent Forms

Sample Document Layout-Adult/General Informed Consent

Adult/General Informed Consent form for Participation in XYZ Study

Funding Source: List complete identification for funding source or None.

IRB approval # (Generated by IRB)

Principal investigator(s)

Name

Complete mailing address

Contact phone number

Co-investigator(s)

Name

Complete mailing address

Contact phone number

Institutional Review Board

Office of Grants and Sponsored Programs

Florida Memorial University

(305) 623-4225

Description of the Study:

This section should include a statement that the study involves research, the purpose of the study, the reason for selecting the subject, the procedures to be used and identification of any procedures which are experimental, and the expected duration of the subject's participation, including anticipated follow-up. These procedures should be explained in as much detail as necessary for the subject to understand. Any procedure which is likely to cause stress, pain, or any other unpleasant reaction should be described so that the person understands fully what they are consenting to.

Risks /Benefits to the Participant:

Subjects should be informed about direct or indirect potential benefits to them or others or the absence of benefits. Elements related to payment (remuneration) are not considered "benefits" to a subject and should be discussed within the Costs/Payments section. Risks should also be specified. All studies are considered to have some risk. Therefore, risk should always be described as at least minimal. Never suggest that there is no risk. For research involving more than minimal risk, explanations as to whether compensation or medical (or other) treatments are available if injury occurs. The section must include the following: "If you have any concerns about the risks or benefits of participating in this study, you can contact [name of principal investigator and advisors/collaborators] or the IRB office at the numbers indicated above." If there are no direct benefits, indicate, "There are no direct benefits."

Initials: _____ Date: _____

Costs and Payments to the Participant:

Costs and Payments to the Participant should be addressed explicitly, including a statement that payments will not be given if that is the case. Describe how payments are made if the subject elects to discontinue participation during the study. If there are no costs or payments involved, you may state, "There are no costs to you or payments made for participating in this study."

Confidentiality and Privacy:

Confidentiality must be specified as well as a description of procedures for protecting privacy, including specific information regarding how data will be stored to insure security and confidentiality. The confidentiality statement must include in the statement a clause that reads "all information obtained in this study is strictly confidential unless disclosure is required by law." This section must also specify that the IRB and regulatory agencies may review research records.

Use of Protected Health Information (PHI):

Whenever PHI is used, the researcher must obtain a valid authorization from the subject via this section of the consent form. If the study involves collecting PHI, the following format should be used:

"As part of this study, you are asked to authorize (specify the specific person(s) by name who will be requesting this information, usually the researcher(s)) access to your records (specify the exact record(s), such as family practice file of Dr. Johnson, or mental health records at the FMU Community Mental Health Center). The purpose of this authorization is to allow the researcher to obtain the following specific information to be used as part of this research study. This information includes: (list here all information you will get, such as EKG results, therapy noted, IQ scores, etc.). You may change your mind and revoke (take back) this authorization at any time, except to the extent that the researchers have already acted based on this authorization. To revoke this authorization, you must write to: (list the primary and co-investigators and their contact information). Your treatment at FMU (or other applicable organization) will not be affected in any way by your refusal to give this authorization or to later decide to revoke authorization. You will not be able to participate in the study procedures if you decide that you will not give authorization. If you allow this transfer of information from your medical file, this information will no longer be protected by federal or state law and, thus, it is possible that this information could be re-disclosed. However, we will protect the confidentiality of this information as discussed in the Confidentiality section. You have the right to refuse to sign this authorization and informed consent. This will not affect your treatment in any manner (add where relevant: but you will be unable to participate in the treatments and procedures associated with this research study).

Initials: _____ **Date:** _____

If PHI is used, add either of the following paragraphs:

Restriction of Access to Records

“You have the right to inspect or copy your Protected Health Information to be used or disclosed as permitted under federal and state law (whichever gives you greater access rights). You also can refuse to sign this agreement. Participating in this study does not affect your rights to inspect or copy your Protected Health Information.”

OR

“Because of the nature of this study, it is necessary to temporarily restrict your access to your medical records in order to insure the validity of the study. You will be restricted from seeing or reviewing the following records during the course of the study: (specify exact records or information). You will be given complete access as defined under federal and state law on (specify exactly when). “

If PHI is not used, the researcher may either add the following paragraph or may eliminate the PHI section:

“This study does not require the disclosure of any Protected Health Information.”

Use of Student/Academic Information:

If information will be collected from educational records, this section must discuss what information will be extracted and how it will be used.

If no student/academic information will be used in the study, this section may be eliminated.

Participant's Right to Withdraw from the Study:

This section must include a statement that the subject understands s/he is free to refuse to participate in or withdraw from the study at any time without adverse affects or loss of benefits. If as a part of withdrawing from the study, the participant may request that his/her data be destroyed when legal, that too should be included. The following example is provided:

“You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect your treatment at the medical center in any way. If you choose to withdraw, you may request that any of your data, which have been collected be destroyed unless prohibited by state or federal law.”

Initials: _____ **Date:** _____

The above may be replaced with the following if the data will not (or cannot be) destroyed or that option is not available to subjects. That information must be stated along with the period of time the data will be kept (e.g., "in perpetuity," "length of the study plus three years," etc.). The following example is provided:

"You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect your treatment at the medical center in any way. If you choose to withdraw, your data will not be destroyed and will be kept for the length of this study."

Other Considerations:

This general statement should be included (in the appropriate person):

"If significant new information relating to the study becomes available which may relate to your willingness to continue to participate, this information will be provided to you by the investigators."

Voluntary Consent by Participant:

This paragraph must be included exactly as written in bold face type:

I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate. All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study, they will be answered by (fill in name). (If applicable: I also voluntarily agree to the release of my PHI as described in this document.) A copy of this form has been given to me. This consent ends at the conclusion of this study.

Participant's Signature: _____ Date: _____
Authorized Representative: _____ Date: _____
Authority of Representative is based on: _____
Witness's Signature: _____ Date: _____

Sample Document Layout for Child Assent Form

Assent for Participation in the XYZ Project

Funding Source: List complete identification for funding source or None.

IRB approval # (Generated by IRB)

Principal investigator(s):

Name

Complete mailing address

Contact phone number

Co-investigator(s):

Name

Complete mailing address

Contact phone number

Institutional Review Board

Office of Grants and Sponsored Programs

Florida Memorial University

(305) 623-4225

Description of the Study:

This should be a simple description of what the child will do written in simple language appropriate to the age of the youngest child for whom the form is intended.

Benefits/Dangers:

This should include basic descriptions of the benefits a participant could expect. If there are no benefits, state "You will not benefit from being in this study." This section should also include basic descriptions of the risks of the study that may include changes of stress, distress, fear, anxiety, or pain. If risks are only minimal, state "we don't think you will be hurt by helping with this study." Also included should be a statement on privacy such as, "Anything you tell us or do for us might be found out by someone else, but we will do everything we can to keep it secret."

Costs/Payments:

This should state either, "If you are in the study, you will not be given anything," or, "If you are in the study, you will be given (list specifically). Be clear on any conditions.

Leaving the Study:

This should state "If you do not like the study, you don't have to help or you may stop at any time, and no one will be angry." (When applicable, include: "If you do stop, you will not get the five dollars you were promised" or whatever is appropriate.) If data may be destroyed, then it should state "Your parents can ask that we get rid of all your work if

Initials: _____ **Date:** _____

they want.” If data may not be destroyed, or must be maintained for a period of time, then it should state “Your information will be kept, even if you leave the study, for three years.” (Substitute the actual length of time the data will be kept).

Use of Student/Academic Information:

If information will be collected from educational records, this section must discuss what information will be extracted and how it will be used.

If no student/academic information will be used in the study, this section may be eliminated.

Other Information:

“If anything happens that would change what we just told you, we will tell you right away.”

Agreement to be in the Study:

The following must be included exactly as written in bold face type:

I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate. All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study, they will be answered by (fill in name). (If applicable: I also voluntarily agree to the release of my PHI as described in this document.) A copy of this form has been given to me. This consent ends at the conclusion of this study.

I have read this or been told about the study. I agree to be in the study.

Child’s Signature: _____ Date: _____

Witness’s Signature: _____ Date: _____

ACKNOWLEDGMENT OF PARENT OR LEGAL GUARDIAN

I have read the preceding and I give consent for my child to participate in this research project. A copy of this form has been given to me.

Parent/Legal Guardian’s Signature: _____ Date: _____

Witness’s Signature: _____ Date: _____

Sample Document Layout-Adolescent Assent Form

Assent for Participation in XYZ Project

Funding Source: List complete identification for funding source or None.

IRB approval # (Generated by IRB)

Principal investigator(s):
Name
Complete mailing address
Contact phone number

Co-investigator(s):
Name
Complete mailing address
Contact phone number

Institutional Review Board
Office of Grants and Sponsored Programs
Florida Memorial University
(305) 623-4225

Description of the Study:

This section should include a statement that the study involves research, the purpose of the study, the reason for selecting the subject, the procedures to be used and identification of any procedures which are experimental, and the expected duration of the subject's participation, including anticipated follow-up. These procedures should be explained in as much detail as necessary for the subject to understand. Any procedure which is likely to cause stress, pain, or any other unpleasant reaction should be described so that the person understands fully what they are consenting to.

Risks /Benefits to the Participant:

Subjects should be informed about direct or indirect potential benefits to them or others or the absence of benefits. Risks should also be specified. All studies are considered to have some risk; therefore, risk should always be described as at least minimal. Never suggest that there is no risk. For research involving more than minimal risk, explanations as to whether compensation or medical (or other) treatments are available if injury occurs. The section must include the following: "If [I/you] have any concerns about the risks or benefits of participating in this study, [I/you] can contact [name of principal investigator and advisors/collaborators] or the IRB office at the numbers indicated above." If there are no direct benefits, indicate "There are no direct benefits."

Initials: _____ Date: _____

Costs and Payments to the Participant:

Costs and payments to the participant should be addressed explicitly, including a statement that payments will not be given if that is the case. If there are no costs or payments involved you may state, "There are no costs to you and you won't be paid for participating in this study."

Confidentiality and Privacy:

Confidentiality must be specified as well as a description of procedures for protecting privacy, including specific information regarding how data will be stored to ensure security and confidentiality. The confidentiality statement must include a clause that reads "all information obtained in this study is strictly confidential unless disclosure is required by law." This section must also specify that the IRB and regulatory agencies may review research records.

Use of Protected Health Information (PHI):

Whenever PHI is used, the researcher must obtain a valid authorization from the potential subject via this section of the consent form. If no PHI is used, the researcher may simply indicate, "This study does not require the disclosure of any Protected Health Information" or not include the PHI section. If PHI is being used, the following format should be used.

"As part of this study, you are asked to let (specify here the specific persons by name who will be requesting this information, usually the researchers) have access to your records (specify the exact record (s), such as family practice file of Dr. Johnson, or mental health records at the FMU Community Mental Health Center). The reason for letting the researcher(s) get the following specific information is so that it can be used as part of this study. This information includes: (list here all information you will get, such as EKG results, therapy notes, IQ scores, etc.). You may change your mind and revoke (take back) this authorization at any time, except to the extent that the researchers have already acted based on this authorization. To revoke this authorization, you must write to: (list the primary and co-investigators and their contact information). Your treatment at FMU (or other applicable organization) will not be affected in any way by saying no to this authorization. You will not be able to participate in the study procedures if you decide that you will not give authorization. If you allow this transfer of information from your medical file, this information will no longer be protected by federal or state law and thus it is possible that this information could be re-disclosed. However, the researchers will protect the confidentiality of this information as discussed in the Confidentiality section. You have the right to refuse to sign this authorization and informed consent. This will not affect your treatment in any manner (add, where relevant, but you will be unable to participate in the treatments and procedures associated with this research study.)

Initials: _____ **Date:** _____

If PHI is used, add either:

Restriction of Access to Records

“You have the right to inspect or copy your Protected Health Information to be used or disclosed as permitted under federal and state law (whichever gives you greater access rights). You also can refuse to sign this agreement. Participating in this study does not affect your rights to inspect or copy your Protected Health Information.”

OR

“Because of the nature of this study, it is necessary to temporarily restrict your access to your medical records in order to insure the validity of the study. You will be restricted from seeing or reviewing the following records during the course of the study: (specify exact records or information). You will be given complete access as defined under federal and state law on (specify exactly when).”

If PHI is not used, the researcher may either use the statement below or may eliminate this section:

“This study does not require the disclosure of any Protected Health Information.”

Use of Student/Academic Information:

If information will be collected from educational records, this section must discuss what information will be extracted and how it will be used.

If no student/academic information will be used in the study, this section may be eliminated.

Participant's Right to Withdraw from the Study:

This section must include a statement that the subject understands s/he is free to refuse to participate in or withdraw from the study at any time without adverse affects or loss of benefits. If as a part of withdrawing from the study the participant may request that his/her data be destroyed when legal, that too should be included. The following example is provided:

“You have the right to refuse to be a part of the study or stop participating. If you do withdraw or refuse to be in the study, it will not affect your treatment in any way. If you choose to withdraw, you may ask that any of your data, which have been collected be destroyed unless prohibited by state or federal law.”

Initials: _____ **Date:** _____

The above may be substituted if the data will not (or cannot be) destroyed or that option is not available to subjects. It must be followed with information as to how long the data will be kept (e.g., “forever” “length of the study plus three years,” etc.). The following example is provided:

“You have the right to refuse to participate or to withdraw at any time, without penalty. If you choose to withdraw, your data will be maintained for the duration of the study.”

Other Considerations:

This general statement should be included (in the appropriate person):

“If we learn important new information about this study, we will tell you and let you decide if you want to stop being a part of the study.”

Voluntary Consent by Participant:

This paragraph must be included exactly as written in bold face type:

I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate. All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study, they will be answered by (fill in name). (If applicable: I also voluntarily agree to the release of my PHI as described in this document.) A copy of this form has been given to me. This consent ends at the conclusion of this study.

Participant's Signature: _____ Date: _____

Witness's Signature: _____ Date: _____

ACKNOWLEDGMENT OF PARENT OR LEGAL GUARDIAN

I have read the preceding and I give consent for my child to participate in this research project. A copy of this form has been given to me.

Parent/ Legal Guardian's Signature _____ Date: _____

Witness's Signature: _____ Date: _____

Sample Document Layout-Parent/Guardian Informed Consent

Parent/Guardian Consent for Participation in XYZ Study

Funding Source: List complete identification for funding source or None.

IRB approval # (Generated by IRB)

Principal investigator(s):

Name

Complete mailing address

Contact phone number

Co-investigator(s):

Name

Complete mailing address

Contact phone number

Institutional Review Board

Office of Grants and Sponsored Programs

Florida Memorial University

(305) 623-4225

Description of the Study:

This should begin "You are being asked to give permission for your child to participate in a research study." This section should then give the purpose of the study, the reason for selecting the subject, the procedures to be used and identification of any procedures which are experimental, and the expected duration of the subject's participation, including anticipated follow-up. These procedures should be explained in as much detail as necessary for the subject to understand. Any procedure which is likely to cause stress, pain, or any other unpleasant reaction should be described so that the parent understands fully what they are consenting to.

Risks /Benefits to the Participant:

Parents should be informed about direct or indirect potential benefits to them or others or the absence of benefits. Risks should also be specified. All studies are considered to have some risk; therefore, risk should always be described as at least minimal. Never suggest that there is no risk. For research involving more than minimal risk, explanations as to whether compensation or medical (or other) treatments are available if injury occurs. The section must include the following: "If [I/you] have any concerns about the risks or benefits of participating in this study, [I/you] can contact [name of principal investigator and advisors/collaborators] or the IRB office at the numbers indicated above." If there are no direct benefits, indicate "There are no direct benefits."

Initials: _____ Date: _____

Costs and Payments to the Participant:

Costs and payments to the participant should be addressed explicitly, including a statement that payments will not be given if that is the case. If there are no costs or payments involved you may state, "There are no costs to you or payments made for participating in this study."

Confidentiality and Privacy:

Confidentiality must be specified as well as a description of procedures for protecting privacy, including specific information regarding how data will be stored to ensure security and confidentiality. The confidentiality statement must include a clause that reads "all information obtained in this study is strictly confidential unless disclosure is required by law". This section must also specify that the IRB and regulatory agencies may review research records.

Use of Protected Health Information (PHI):

Whenever PHI is used, the researcher must obtain a valid authorization that is included in this section of the consent form. If no PHI is used, the researcher may simply indicate, "This study does not require the disclosure of any Protected Health Information."

If PHI is being used, the following format should be used:

"As part of this study, you are being requested to authorize (specify here the specific persons by name who will be requesting this information, usually the researchers) access to your records (specify the exact record (s), such as family practice file of Dr. Johnson, or mental health records at the FMU Community Mental Health Center). The purpose of this authorization is to allow the researcher to get the following specific information to be used as part of this research study. This information includes: (list here all information you will get, such as EKG results, therapy noted, IQ scores, etc.). You may change your mind and revoke (take back) this authorization at any time, except to the extent that the researchers have already acted based on this authorization. To revoke this authorization, you must write to: (list the primary and co-investigators and their contact information). Your treatment at FMU (or other applicable organization) will not be affected in any way by your refusal to give this authorization. You will not be able to participate in the study procedures if you decide that you will not give authorization. If you allow this transfer of information from your medical file, this information will no longer be protected by federal or state law and thus it is possible that this information could be re-disclosed. However, we will protect the confidentiality of this information as discussed in the Confidentiality section. You have the right to refuse to sign this authorization and informed consent. This will not affect your treatment in any manner (add, where relevant, but you will be unable to participate in the treatments and

Initials: _____ **Date:** _____

procedures associated with this research study).

If PHI is used, add either:

Restriction of Access to Records

“You have the right to inspect or copy your Protected Health Information to be used or disclosed as permitted under federal and state law (whichever gives you greater access rights). You also can refuse to sign this agreement. Participating in this study does not affect your rights to inspect or copy your Protected Health Information.”

OR

“Because of the nature of this study, it is necessary to temporarily restrict your access to your medical records in order to insure the validity of the study. You will be restricted from seeing or reviewing the following records during the course of the study: (specify exact records or information). You will be given complete access as defined under federal and state law on (specify exactly when).”

“This authorization expires at the end of this study.”

If PHI is not used in the study the researcher may either use the sentence below or eliminate the PHI section completely from the consent form:

“This study does not involve Protected Health Information.”

Use of Student/Academic Information:

If information will be collected from educational records, this section must discuss what information will be extracted and how it will be used.

If no student/academic information will be used in the study, this section may be eliminated.

Participant's Right to Withdraw from the Study:

Participant's right to withdraw from the study must include a statement that the parent understands s/he is free to refuse to allow their child to participate in or to withdraw their child from the study at any time without adverse effects or loss of benefits, and that they may ask, if the child is withdrawn, that the data be destroyed except when illegal. It also requires a statement as to whether there will be any consequences to the child and/or parent as a result of the withdrawal.

Initials: _____ **Date:** _____

For example: “You have the right to refuse for your child to participate or withdraw your child at any time. If you do withdraw your child, it will not affect your child’s treatment at the medical center in any way. If you choose to withdraw your child, you may request that any data which has been collected be destroyed unless prohibited by state or federal law.”

If the data will not (or cannot be) destroyed or that option is not available to subjects then that must be stated along with the period of time the data will be kept (e.g., “in perpetuity,” “length of the study plus three years,” etc.). The following example is provided:

“You have the right to refuse for your child to participate or withdraw your child at any time. If you do withdraw your child, it will not affect your child’s treatment at the medical center in any way. If you choose to withdraw your child, your child’s data will not be destroyed and will be retained for the length of the study plus three years.”

If the study involves the parent participating, as well as the child, this section must account for that participation. For example:

“You have the right to refuse to participate or withdraw at any time. You also have the right to refuse for your child to participate or to withdraw your child at any time. If you, or your, child withdraws, it will not affect you or your child’s treatment at the medical center in any way. If you choose to withdraw your child, your child’s data will not be destroyed and will be retained for the length of the study plus three years.”

Other Considerations:

This general statement should be included (in the appropriate person):

If significant new information relating to the study becomes available which may relate to your willingness to have your child continue to participate, this information will be provided to you by the investigators.”

Initials: _____ **Date:** _____

Voluntary Consent by Participant:

This paragraph must be included exactly as written in bold face type:

I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily give consent for my child to participate. All of my questions concerning the research have been answered. I hereby agree to have my child participate in this research study. If I have any questions in the future about this study, they will be answered by (fill in name). (If applicable: I also voluntarily agree to the release of my PHI as described in this document.) A copy of this form has been given to me. This consent ends at the conclusion of this study.

Child's Name: _____

Parent's/Guardian Signature: _____ Date: _____

Witness's Signature: _____ Date: _____

Appendix E
FMU-IRB Submission Form for Continuation/Renewal/Revision of
IRB Approved Studies

FMU-IRB Submission Form for Continuation/Renewal/Revision of IRB Approved Studies

Instructions: In order to comply with federal regulations as well as to conform with guidelines of the university's Institutional Review Board (IRB), the principal investigator is required to complete all of the following items for projects that will continue beyond the one year approval granted by the IRB or which have been revised. Investigators are advised to submit this form and all necessary documents at least three months before the expiration date of the study's approval. Please contact your center representative for information regarding submitting this form.

For further information, refer to the *Procedure Manual for Research with Human Subjects*. Please attach additional typed sheets if there is inadequate room for your answers to any question. Fill in all questions; if not applicable, write NA.

I. General Information

Project Title

Continuation/Renewal _____

Revision _____

Initial IRB Approval Date _____

Subsequent Approval Date(s) _____

Performance Site(s)

Principal Investigator Information

Name		Relationship to FMU:
Office Mailing Address (Home Address if Student):		Faculty <input type="checkbox"/>
		Staff <input type="checkbox"/>
		Student <input type="checkbox"/>
Office Phone (Home Phone if Student):	Alternate Phone	Office Phone (Home Phone if Student):
Email Address:		Fax:

Principal Investigator's Signature _____ Date _____

Please list all Co-Investigators and their contact information:

Co-Investigator	E-mail address	Contact Phone Number

II. ATTACH A COPY OF THE CURRENT PROTOCOL AND CONSENT FORMS

III. Funding Information

If this protocol is part of an application to an outside agency, please provide:

- A. Source of Funding _____
- B. Project Title (if different from above) _____
- C. Principal Investigator (if different from above) _____
- D. Type of Application: Grant Subcontract Contract Fellowship
- E. Date of Submission _____

IV. Cooperative Research

Cooperative research projects are those that involve more than one institution and can be designed to be both multi-site and multi-protocol in nature. If this proposal had been submitted to another Institutional Review Board, please provide:

Name of Institution _____
 Contact Person _____
 Renewal Date: _____
 Revisions Approved? ____ Yes ____ No ____ NA _____
 IRB Recommendation _____

V. Subject/Patient Information

A. Types of Subjects/Patients (check all that apply):							
	Fetus in Utero/ non-viable fetuses/ abortuses	Newborns/ Infants	Children (aged 2-7)	Children (age 8-12)	Adolescents (aged 13-17)	Adults (18+)	Pregnant Women
Enrolled #							
Future #							
Do any of the checked subjects belong to a special population (e.g., prisoners, mentally disabled)? Yes <input type="checkbox"/> No <input type="checkbox"/>							
If you answered yes, please specify in detail the nature of the special population(s)?							

B. Other (Check all that apply):
Use of investigational drugs or devices <input type="checkbox"/>
Information to be collected may require special sensitivity <input type="checkbox"/> (e.g. substance abuse, sexual behavior) Please specify:

G. Does this study involve the use of protected health information (PHI) from client charts or other records? Yes <input type="checkbox"/> No <input type="checkbox"/>
If Yes, will consent be obtained from the client for all PHI collected? Yes <input type="checkbox"/> No <input type="checkbox"/>
If consent is not obtained, which of the following applies?
<input type="checkbox"/> The data will be collected in a fully de-identified data set.
<input type="checkbox"/> The data will be collected as part of a limited dataset agreement.
<input type="checkbox"/> The data will be collected under a waiver from a duly constituted privacy board. (Please attach a copy of the waiver to this form).

VI. Changes

A. Are there any changes since initial IRB approval (or last renewal, if applicable)?
Yes _____ No _____

If Yes, please list all proposed changes:

Change(s) previously approved (you may attach a separate page if necessary):

Attach additional documentation as necessary to support any previously unapproved changes.

VII. Summary of Results to Date (CONTINUATION/RENEWAL ONLY)

VIII. Progress Report (CONTINUATION/RENEWAL ONLY)

Total Number of Subjects Entered into Study to Date _____
Total Number of Subjects Completing the Study to Date _____
Total Number of Subjects Currently Enrolled _____
Total Number of Subjects Who Withdrew _____
Additional Subjects to be Recruited _____
Expected time until completion of the Study: _____

List ALL adverse or unexpected reactions and their resolution (if none, state none).
Attach copies of all adverse reaction reports, even if previously reported.

Unexpected/Adverse Reaction Resolution

IX. Consent Forms

As IRB and legal requirements continually evolve, all consent forms must be reviewed using current IRB guidelines as found on the IRB website. The investigator certifies that these requirements have been reviewed and that the attached consent forms have been modified as necessary to meet current IRB guidelines: _____ Yes _____ No

If No, please explain (e.g., requirement of grantor or other reason):

Do the consent forms require translation? _____ Yes _____ No
If yes, please attach the original English version along with all translations.

X. Recruitment Materials

Are any changes or updates proposed to the recruitment material?
_____ Yes _____ No

If Yes, please describe the changes and include samples of the old and new materials.

Appendix F
Review Preparatory to Research (Covered Entity Workforce) Form

Review Preparatory to Research (Covered Entity Workforce) Form

Name: _____ Signature: _____

Center: _____

Date: _____

IRB Center Representative Approval
(signature): _____

Date: _____

A. Reason for preparatory collection of PHI

B. Description of PHI and population to be used

C. I attest to the following: (Please initial by each statement)

- 1) The use of PHI is solely for review in preparation for research and will not be used in any research prior to IRB approval.
- 2) The PHI will not leave the health care facility.
- 3) The PHI is necessary for purposes of preparatory research.
- 4) The patients will not be contacted unless researcher is patient's healthcare provider or member of clinic staff.

Appendix G
IRB Waiver Request Form (Preparatory Research-Non-covered Entity Workforce) Form
For Requests Submitted to FMU IRB

**IRB Waiver Request Form (Preparatory Research-Non-covered Entity Workforce)
Form for Requests Submitted to FMU-IRB**

Note: This form is to be used only for preparatory research. All waivers involved in actual research projects are required to be part of the normal application required by the IRB

Section 1: To be completed by researcher (attach extra pages as needed)

Name of Researcher: _____

Title of Research Project:

Describe the specific Protected Health Information that is needed for the preparatory research.

Describe the reasons why the preparatory research could not practicably be done without the Protected Health Information listed above.

Describe the reasons why the preparatory research could not practicably be done without a waiver of authorization (i.e., describe reasons why it is not practical to have patients sign an authorization form or to gain authorization in another manner).

Describe why the information you need could not be attained through a de-identified data set.

Describe your plan to protect identifiable information from improper uses and disclosures. Include information on where the information will be stored and who will have access to the information.

Describe your plan to destroy identifiable information at the earliest opportunity consistent with the conduct of your research protocol, including a description of when and how the information will be destroyed.

Explain why there is no other alternate way to do this other than the granting of a waiver. Please note that neither the inconvenience nor cost of a possible alternative is a valid reason for the granting of a waiver.

By my signature below, I attest that the Protected Health Information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of Protected Health Information would be permitted by this subpart. I also agree that I will not contact any potential research subject without express IRB permission.

Signature of Researcher: _____

Title: _____

Relationship to FMU: _____

Address: _____

Phone contact: _____ Fax: _____

E-mail contact: _____

Section II: To be completed by the IRB

The waiver request was reviewed by Full IRB review on _____.

The IRB has determined that the following criteria have been met (please check all that apply):

_____ There is an adequate plan to protect the identifiable information from improper use and disclosure.

_____ There is an adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

_____ The researcher's signature above provides adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

_____ The research could not practically be conducted without the requested waiver of authorization.

_____ The research could not practically be conducted without access to and use of the protected health information and there is no alternative manner which does not require a waiver to conduct this research.

IRB Determination

The above criteria have been met and the request is APPROVED _____

Some of the criteria have not been met and the request is DENIED _____

Signature of IRB Officer _____

Date of IRB Action: _____

Appendix H
Adverse Event Report

**Florida Memorial University
Institutional Review Board for Research with Human Subjects (IRB)
Serious Adverse Event/Sentinel Event Report**

Date of this Report:	
IRB Protocol #:	FMU Center/College:

Project Title

Principal Investigator Information

Name		Relationship to FMU: Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/>
Office Mailing Address (Home Address if Student):		
Office Phone (Home Phone if Student):	Alternate Phone	
Email Address:		Fax:

Study Sponsor:
Has the sponsor been notified? Yes <input type="checkbox"/> No <input type="checkbox"/>
Date of Notification:

Adverse Event Information

Submit 1 Adverse Event Report for each subject. You may use additional sheets to describe the nature of the adverse event. If a separate notification is required for sponsored studies and/or regulatory agencies, please include a copy of that notification.

Participant #	Date of Adverse Event	Description of Adverse Event	FMU Subject? Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the Adverse Event Serious? Yes <input type="checkbox"/> No <input type="checkbox"/>	Was the Adverse Event Unexpected? Yes <input type="checkbox"/> No <input type="checkbox"/>	Was the Adverse Event Unanticipated? Yes <input type="checkbox"/> No <input type="checkbox"/>	Study Related Adverse Event? Yes <input type="checkbox"/> No <input type="checkbox"/>
Should the protocol and/or consent forms be revised Yes <input type="checkbox"/> No <input type="checkbox"/>		Will additional information be given to enrolled subjects? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If Yes, please submit a copy of the corrected amendment forms with bold changes and a clean copy incorporating the changes.			

Principal Investigator's Signature: _____ Date: _____

**Florida Memorial University
Institutional Review Board
IND Safety Report**

Date	IRB Protocol #
Principal Investigator	FMU College

Project Title _____

Study Sponsor _____

IND Safety Report dated _____

Serious Adverse Event / Sentinel Event Information

Description of Serious or Sentinel Event	Date of event

I have personally reviewed the IND safety report of a serious adverse event.

Principal Investigator

Date

DEFINITIONS:

Adverse Experience (also called adverse event) is an untoward occurrence in a trial subject as a result of participation, including being administered a pharmaceutical product, an experimental treatment, or other study related activity.

- The AE need not have a relationship with the study.
- If the AE has a reasonable possibility of having causal relationship with treatment, it would be defined as an adverse reaction

Some categories of AE are defined as serious.

IND regulations and the ICH GCP guidelines define **Serious Adverse Event** as an untoward medical occurrence that:

- Results in death
- Is life threatening
- Requires in-patient hospitalization (admission of >24 hours, not an ER visit)
- Prolongs existing hospitalization
- Results in persistent or significant disability /incapacity
- Congenital anomaly/birth defect

And **Sentinel Events** defined by HRPP are:

- Death
- Major permanent loss
- Permanent loss of physical or psychological function not related to natural course of subject's illness or underlying condition

IND Safety reports are generated when a serious adverse event which may be related to the study drug and not expected occurs in any protocol using the study drug.